E.M.C.D.D.A.

European Monitoring Centre for Drugs and Drug Addiction

Early-warning system on new synthetic drugs

Guidance on implementation

Information on the EMCDDA can be found on its website **(http://www.emcdda.org)**.

A great deal of additional information on the European Union is available on the Internet.

It can be accessed through the Europa server (http://europa.eu.int).

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Introduction

Within the framework of the Joint Action of 16 June 1997, the Early-warning System (EWS) aims to create a mechanism for the rapid exchange of information on the production, traffic, use and risks of new synthetic drugs.

Taking into account the experience acquired by all actors involved since the adoption of the Joint Action, some guidance is presented here to contribute to improving the functioning of the EWS. This has been put together by analysing the main elements of the system and identifying the developments needed.

This document should be regarded as a practical booklet on how the EWS functions and it will continue to be modified in the future in light of new experience and additional knowledge. Within the framework of the EMCDDA's tasks of preparing for the enlargement process, it has been considered useful to publish this booklet so as to help the candidate countries to enhance their knowledge of the Joint Action, and especially on the challenges of setting up an EWS on new synthetic drugs.

We would like to thank very much all the National Focal Points (NFPs) of the EMCDDA's Reitox network for their valuable contribution to this booklet.

Alain Wallon
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EMCDDA Joint Action Coordination
Lisbon, 29 June 2001

A. Scope

Background

The scope of the Joint Action is set out in article 2.

This Joint Action concerns new synthetic drugs which are not currently listed in any of the Schedules of the 1971 United Nations Convention on Psychotropic Substances, and which pose a comparable serious threat to public health as the substances listed in Schedules I or II thereto and which have a limited therapeutic value. It relates to end-products, as distinct from precursors. (JA article 2)

Explanation

Common definitions have been developed as elaborated below.

	Definition
Synthetic drug	A psychoactive substance that is manufactured through a chemical process in which the essential psychoactive constituents are not derived from naturally occurring substances.
New synthetic drug	A synthetic drug which presents a new phenomenon on the market either: a) because it has been created as a new molecule or compound; or b) because of its new mode of use (for psychotropic effects).
New synthetic drug within the scope of the Joint Action	A synthetic drug which: a) is not included within any Schedule of the UN Convention on Psychotropic Substances; and b) has similar characteristics to substances listed in Schedules I or II of the above-mentioned Convention, meaning that it poses a serious threat to public

	health and that it has limited therapeutic value.
Early-warning system (EWS)	A system aiming to detect a significant risk to public health and to inform the relevant authorities and services as quickly as possible.
EWS of the Joint Action	An EWS to detect new synthetic drugs which pose a serious threat to public health and which are of limited therapeutic value. The EWS should make it possible to provide the authorities of the Member States with rapid information about new substances and their modes of consumption in order to identify dangerous substances.
Pattern of use	A broad concept defined operationally in terms of: • different drugs and combinations used; • frequency/intensity of use; • mode of administration; • characteristics of main user groups; • main settings of use; • main effects/consequences reported.
Chemical precursors	Chemical products used in the laboratory fabrication of either synthetic or non-synthetic drugs. In the fabrication of a synthetic drug only chemical compounds are involved: precursors, reagents and additives. For non-synthetic drugs, chemicals are used at different stages in the transformation of the raw natural substance into the end product. Precursors themselves are generally the result of combining and processing various chemicals, called pre-precursors, and reagents.
Interagency cooperation	The adoption of the Joint Action by the Council of the European Union, has given the EMCDDA a clear mandate to coordinate, together with Europol, the collection

Interagency cooperation *(cont.)*	and exchange of information on new substances as they appear on the market. A cooperation system has been established between, on the one hand, Europol for the collection of law-enforcement information through its Europol National Units (ENUs) and, on the other hand, the EMCDDA, through the National Focal Points (NFPs) of the Reitox network, for the collection of information on the social and health aspects.

(See also Part F: Extended glossary)

B. Actors

Background

The role of each actor set is set out in article 3 of the Joint Action.

Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the production, traffic and use of new synthetic drugs to the Europol Drugs Unit (EDU) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), taking into account the respective mandates of these two bodies. The EDU and the EMCDDA shall collect the information received and communicate this information in an appropriate manner immediately to each other and to the Europol National Units and the representatives of the Reitox-network of the Member States, to the Commission and the European Agency for the Evaluation of Medicinal Products. (JA article 3)

Explanation

The role and interaction of the actors is explained in more detail below.

Member State	As the Joint Action is a binding Council decision [1], it is the responsibility of the national government/ administration to guarantee that its Europol National Unit (ENU) and National Focal Point (NFP) have in place the appropriate infrastructure and the resources and capacity to obtain and provide the information requested.
EMCDDA	The Joint Action gives the EMCDDA the mandate to ensure that the network remains operational so as to be able to obtain the information required. As such, the EMCDDA ensures the coordination of its network in the collection and provision of information, which is centralised, quality-checked and completed (as far as possible) by the Centre. The EMCDDA

[1] The Joint Action on new synthetic drugs has the same legal value as the founding regulation of the EMCDDA.

EMCDDA *(cont.)*	then reports this information to Europol for for fine-tuning the information received, among others. Subsequently, the EMCDDA reports back to the network, as well as to the Commission and the European Agency for the Evaluation of Medicinal Products (EMEA).
Reitox National Focal Point (NFP)	The NFP guarantees the functioning of its early-warning system network for rapid detection and collection of information. The NFP sends the information to the EMCDDA, at the same time taking steps to validate it.
Europol	Europol has the same mandate as the EMCDDA to ensure that its network for rapid detection and exchange of information in the Member States remains operational.
Europol National Unit (ENU)	The ENU guarantees the functioning of its national network of law-enforcement sources.
European Commission	The European Commission receives the information from the EMCDDA or Europol, and may contribute with information on chemical precursors, in respect of Council Regulation 3677/90 and Council Directive 92/109/EEC (see JA article 2).
European Agency for the Evaluation of Medicinal Products (EMEA)	The EMEA receives the information from the EMCDDA or Europol, and may contribute with information on the medicinal use and pharmacological aspects of new synthetic drugs.

C. Information exchange tools

Levels

Two different levels of information exchange are distinguished in two separate sub-articles (a and b) of article 3 of the Joint Action mandate:

- a first level for the early detection of a new substance ('rapid alert') the aim of which is to initiate the mechanism of the Joint Action, informing the other partners on the emergence of the substance on the market. In this phase 'rapid reaction' is the key concept; and
- a second level for the collection of as much relevant information about this substance which aims to provide a more complete picture at European level. At this level 'to complete the picture' is the key concept.

Both these levels of information exchange require a proactive approach and are important in preparing a basis for a decision of the authorities to carry out the risk assessment of the substance.

Information

Three types of information are requested:

- information useful for the identification of the substance;
- information related to the use of the substance; and
- information on the consequences of this use.

When the substance is first detected, the information about its identification (physical, chemical and street name) is very important to allow the other partners to check whether it is also present on the market in their respective countries. The information about use and consequences cannot be exhaustive if the substance is new. The 'rapid reaction' phase requires only a first indication on use and consequences.

During the second level of information gathering, focus should be placed on providing complementary information on the substance's identification (production process) and on providing all relevant information on its use and consequences.

Level 1

Background

The Joint Action specifies the information required at level 1.

The information referred to in paragraph 1 shall include:
A chemical and physical description, including the name under which a new synthetic drug is known,

- *information on the frequency, circumstances and/or quantities in which a new synthetic drug is encountered,*
- *a first indication of the possible risks associated with the new synthetic drug,* (JA article 3, 2)

Explanation

The requirements at level 1 of the information exchange are set out in more detail below.

Information required	
A chemical and physical description, including the name under which a new synthetic drug (NSD) is known	The chemical composition is the key element of identification (scientific name). It is also important to know whether samples on the market contain the NSD only or if it is mixed with other substances. In this case, information on the average content and range of the NSD is needed. The physical description of the different forms in which the NSD is encountered will assist the visual identification of the substance on the market. It is therefore important to describe the form (pill, powder, capsule), colour, shape, size, weight, logo and other relevant markings. The name(s) and synonyms under which the NSD is known (street name) is also relevant and could help to determine whether it was sold as itself or as something else (e.g. paramethoxymethylamphetamine or PMMA sold as 'ecstasy').

Information on the frequency, circumstances and/or quantities in which a new synthetic drug is encountered	This refers to the information available about the circumstances in which the drug is encountered, especially: • number of occurrences (e.g., seizures, deaths); • quantities; • dates and places where found; and • circumstances of findings (e.g., rave parties).
A first indication of the possible risks associated with the new synthetic drug	Although knowledge of risks is generally limited at this stage, preliminary information might include immediate effects reported (symptoms, onset of action, intoxication, adverse reactions, mixtures with other drugs).

Level 2

Background

For level 2, the Joint Action specifies the need for more detail.

And, (the information referred shall include), as far as possible:

- *information on the chemical precursors,*
- *information on the mode and scope of the established or expected use of the new synthetic drug as a psychotropic substance,*
- *information on other use of the new synthetic drug and the extent of such use,*
- *further information on the risks of use of the new synthetic drug, including the health and the social risks.* (JA article 3,2)

Explanation

The requirements at level 2 of the information exchange are set out in more detail below.

Information required	
Information on the chemical precursors	Relevant information on precursors used in and needed for the production process, and, if possible, information on the availability of the precursors at national level (e.g. industrial use).
Information on the mode and scope of the established or expected use of the new synthetic drug as a psychotropic substance	Information focused on the use of the NSD as a psychotropic substance, and in particular: • the type and patterns of use: to what extent the user knows what drug he is taking or whether the user believes it is something else (e.g. 'ecstasy'), the effects expected or searched for by the user, the user's purpose (experimental, recreational, social), the route of administration, combination with other substances, knowledge and perceptions, etc.; • information from local services (observed effects, attitudes of users);

	• the types of users – age, gender, social aspects, etc.; and • the types of places – rave parties, discos, bars, private.
Information on other use of the new synthetic drug and the extent of such use	Information on the use, other than psychotropic, such as medical, nutritional, esthetical, performance, industrial, etc. In particular the information available on users, circumstances and the extent of such use.
Further information on the risks of use of the new synthetic drug, including the health and the social risks	At this stage the information should be focused in more detail on the reported effects, in particular: • the immediate effects; • the short-term effects (if available); and • the medium-term effects (if available). These effects could be presented in the various relevant fields (physical, psychological, individual behaviour, and social). Referring to the EMCDDA's risk-assessment guidelines could be useful for the collection of this information.

D. Reporting and feedback

Background

The Joint Action outlines the procedure to be followed.

The EDU and the EMCDDA shall collect the information received and communicate this information in an appropriate manner immediately to each other and to the Europol National Units and the representatives of the Reitox-network of the Member States, to the Commission and the European Agency for the Evaluation of Medicinal Products. (JA article 3,1)

Explanation

Communication	
Between ENU and Europol	Independently of the communication between ENU and Europol (Europol's remit), the contacts between the NFPs and the law-enforcement sources are important.
Between the EMCDDA and NFPs (feedback)	Reporting forms and a feedback templates are used. Interactive communication tools for use between the EMCDDA and the NFPs through the Reitox website have been developed.
To the Commission	The Commission Focal Point receives the same information as the other Focal Points. The Commission also receives the EMCDDA/Europol 'Article 3 reporting form on NSD' and the EMCDDA/Europol Progress Report on NSD.
To the EMEA	The EMEA receives the same information as the Commission.
Between the NFP and its national networks	The NFP provides feedback to the partners in its national network. These partners provide all relevant information to the NFP (bottom-up and top-down).

E. Structure of national sources for the early-warning system

Background

The Joint Action outlines the respective responsibilities within the Member States for providing the necessary information.

Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the production, traffic and use of new synthetic drugs to the Europol Drugs Unit (EDU) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), taking into account the respective mandates of these two bodies. (JA article 3)

Explanation

When considering an appropriate structure for national EWS sources, it is useful to bear in mind the following questions:

- How does each Member State ensure that its Europol National Unit and its Reitox National Focal Point obtain the information requested?
- How is the information collection organised in each Member State?
- How is this information analysed, cross-checked and validated?

The following key elements have been identified.

Key elements	
Part of a general national system to monitor drug use	• National coverage • Coordination body • Political support • Data collection and feedback tools • Validation system

Part of a general national system *(cont.)*	• Agreed criteria and procedures • Regular meetings and support activities
Health and social sources	• Support of health authorities for the EWS • Partnership with relevant services
Law-enforcement sources	• Horizontal coordination and partnership with the ENU and national law-enforcement agencies • Rapid access to seizures data • Rapid access to forensic reports • Access to information from prosecution services
Sources used to monitor emerging trends	• Prevention units/low-threshold programmes • Outreach/street workers • On-site prevention programmes/pill-testing interventions • Qualitative researchers
Linked to the clinical network	• Rapid access to clinical data • Networking sources (emergency wards, poison units, non-forensic labs, GPs/medical on-site interventions)
Linked to the network of forensic and toxicological laboratories	• Information map of laboratories • Access to toxicological analysis • Regular two-way information flows • Access for laboratories to electronic forum/databases

A suggested structure for these sources is illustrated opposite.

Suggested structure				
Health and epidemiology	Treatment sources	Outreach sources	Law-enforcement sources	Others
(Reporting) Forms in electronic version: real-time responses Links with laboratories				
National Focal Point (validation and notification)				

(Please also refer to the Checklist on page 32.)

Extended glossary

The purpose of the extended glossary is to explain in more depth procedures and definitions of key terms and concepts from the perspective of the EMCDDA.

1. A new synthetic drug

The scope of the Joint Action (article 2) considers synthetic drugs [2] which are:

- *not currently listed under any of the Schedules of the 1971 UN Convention on Psychotropic Substances*
  These may, however, already be controlled by national legislation in one or several EU Member States.
- *posing a comparable serious threat to public health as the substances listed in Schedules I or II of the Convention*
  In general, little sound knowledge is available about a new substance appearing on the drug scene. Consequently, a comparison with the effects of scheduled substances could turn out to be difficult or impossible at a first stage. This explains the importance given by the Joint Action mechanism to the collection and exchange of information (article 3) and to the scientific assessment of health and social risks (article 4).
- *with limited therapeutic value*
  This criterion may exclude drugs with a well-recognised therapeutic value, meaning that it has a current legitimate use and that it cannot be replaced with another substance if this causes important medical and commercial consequences. This particular aspect has also to be assessed (article 3,2; article 4).

[2] Synthetic drugs cover a wide range of types/groups of substances. The date of 'invention' of each of these drugs is not an indication for whether the drug should be considered as new in the framework of the Joint Action. For example, MDMA was patented by Merck in Germany in 1912 and Shulgin's list of phenetylamines appeared in 1991.

2. The grey zone

Diverted medicines which have a recognised therapeutic value (e.g. ketamine) are concerned by a number, but not all, criteria of the Joint Action (article 2). These are non-scheduled synthetic drugs, appearing in similar conditions of use as scheduled synthetic drugs and which may pose comparable health problems to users. Diversion from legitimate supply and/or the scale of trafficking are also important criteria.

The Joint Action only focuses on synthetic drugs which can be classified in Schedules I and II of the 1971 UN Convention. This definition excludes de facto from the procedure of article 5 all substances with a well-established therapeutic value. However, the above-mentioned diverted medicines could be taken into consideration by the responsible political bodies (Commission and Council) in the course of the further development of the Joint Action system.

3. An early-warning system

In general, early-warning systems are defined as information systems used to obtain an early indication on possible risks (industry, environment, health), with the main objective being to prevent the spread of negative consequences through quick responses and preventive action.

Within the framework of the Joint Action, an early-warning system is a system which proves its capacity to detect a new substance and, with a high degree of probability, to identify this new synthetic drug within a short delay from the moment it appears on the national market and/or in the territory (transit flows). The capacity to do this is determined by the coverage and sensitiveness of the national network and by its rapidity in collecting, exchanging, centralising and validating the information for transmission to the relevant partners.

Although this EWS should specifically respond to the need for rapid detection and identification of a substance, it should also have the capacity to 'complete the picture' as is clearly indicated in the two separate sub-articles (a and b) of article 3 of the Joint Action.

When further developed, this EWS may also be able to contribute to identifying and monitoring emerging trends. However, a clear distinction should be made and maintained between, on the one hand, the specific objectives, information collection system and strict delivery procedures of the Joint Action (EU Council decision) and, on the other hand, the collection and dispatching of information on emerging trends. The latter is a complementary

project, which is not bound by a legal text such as the Joint Action and which aims to cover all kinds of drugs and user groups.

4. A trend (emerging, stabilising, decreasing)

Definitions

Trend: Consistent changes in the same direction observed in successive measures of a specified phenomenon over a given period of time.

Trend in drug use: A trend (as defined above) in the prevalence or pattern of use of specified drugs.

New trend: A trend in the use of drugs in a given population or community which has not been observed before in that population or community within a defined historical period.

System to monitor trends in drug use: A broad concept covering mechanisms for the systematic collection of information that can detect and track trends in the prevalence and patterns of drug use, independently of whether the drugs are new or not, natural or synthetic. The coverage of different information sources varies – as does the way in which data collection structures are organised – but it is likely to include data from the EMCDDA's five key epidemiological indicators as well as from other less standardised sources such as local monitoring systems, qualitative 'leading edge' indicators, etc.

Context and objectives

As with all trends by definition, trends in drug use are not immediately established as such, even if they are sometimes identified before they stabilise, as was the case for 'ecstasy'.

From the mid-seventies onwards, drug information systems have focused on opiates and injectors and have not demonstrated the capacity to detect and identify emerging trends in drug use, in particular among young users. Thus it has been realised that, to be predicted, monitored and assessed at an early stage, a new trend will require more sensitive information-collection methods, closer to frontline drug use. Main methods used in this area are networking qualitative researchers, screening youth media and Internet sites or chat-rooms, launching short but targeted ethnographic studies among users, introducing selected new questions in regular surveys, etc.

5. The synergies and differences between the EWS of the Joint Action and the existing systems for monitoring new and emerging trends

The functions of the EWS on NSD and of the Emerging Trends project are different. The EWS of the Joint Action aims to detect a new substance, not identify a potential trend. The rapid reaction mechanism of the Joint Action's EWS has been defined precisely to avoid the situation of the use of a new synthetic drug developing as a trend.

To be sound-based and scientifically validated, the process of identifying an emerging trend needs to track changes over a period of time in order to verify their potential to develop and stabilise as a trend, and to predict further evolution, if possible. Hard data are essential and sources need to be developed and understood in the light of qualitative investigations. Even though some information to be collected for the detection and tracking of a trend could benefit from the capacity of the network put in place for the Joint Action's EWS, neither the tasks nor the outputs are the same.

On the other hand, qualitative information compiled for the purpose of understanding emerging trends, especially in recreational settings where synthetic drugs are commonly used, could provide useful insights into the context within which new synthetic drugs are used.

In conclusion, the synergies between the EWS and the emerging trends systems are:

- the sensitiveness of the system to monitor new trends can contribute to detecting the use of new substances such as NSD;
- the focus of trend monitoring systems on users and on social aspects could contribute to the EWS as regards information on the context in which the NSD is used and the risks linked to it, as well as on the effects reported by the users; and
- the information collected through the EWS gives, as far as possible, a picture on the use of a NSD at European level.

6. A precursor

Precursors are chemical products used in the fabrication in laboratories of synthetic or non-synthetic drugs. In the fabrication of a synthetic drug, only chemical compounds are involved: precursors, reagents and additives. For non-synthetic drugs, chemicals are used at the different stages in the transformation of the raw substance into the end product. Precursors themselves are generally the result of combining and processing various chemicals, called pre-precursors, and reagents.

Reagents are chemicals used in the fabrication of synthetic drugs to stimulate reaction in the different precursors, separately or together, during the process of synthesising the end product.

Additives are compounds which are not used to stimulate a chemical reaction between precursors in the synthesis process, but rather to facilitate this reaction (e.g. dilution) or to filter a liquid solution, or to obtain the final form, consistency, colour, etc. of the synthetic end product.

Impurities are non-desired effects of the fabrication process, at one or more of its different stages (filtering, tableting and packaging). Along with other elements, impurities may provide useful information to forensic laboratories and other law-enforcement services for determining the profile of drugs for intelligence purposes.

End product: after fabrication, the final compound to be consumed by drug users, in its different possible forms (tablets, powder, liquid, pure or mixed with other substances).

7. The availability of reference samples

Definitions [3]

Sample: In laboratory analysis, the equivalent to specimen; it is a representative portion of whole material (e.g. a seizure of n units) to be tested.

Reference sample: Sample of a drug which serves as a reference for various purposes, in particular in forensic science, for example to verify the presence of the same drug in another sample.

Control sample: A reference sample used as a standard for verifying or checking the findings of an experiment.

Pure standards: Samples of a pure substance, (whereas 'reference samples' may contain various components).

Certified samples: Reference samples in which one or more of the property values has been certified by a technical procedure, accompanied by (or traceable to) a certificate or other documentation that has been issued by a certifying body.

Reference standards: A standard, generally of the highest quality available at a given location, from which measurements at this location are derived.

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[3] United Nations International Drug Control Programme (1995), 'Glossary of Terms for Quality Assurance and Good Laboratory Practices', Vienna.

Context and objectives

The availability of reference samples is important for forensic and toxicology laboratories when they want to identify a drug, especially in the case where the drug is new and limited scientific literature on it is available to them. The best and most cost-effective way of identifying a new drug is to match the sample transmitted to the laboratory for analysis with a reference sample, applying the same analytical methods to both samples.

A reference sample is also important as laboratories need to provide accurate information not only on seizures of a particular drug in Member States, but also on its presence in body fluids in accident, emergency and post mortem cases. Such information is also a key element of the technical annexes of the EMCDDA's guidelines upon which the risk assessment is based.

The availability to laboratories of reference samples would also enhance the process of building up a laboratory network for the purpose of the Joint Action (see point 8 below).

At first glance, the issue of transmitting a sample of a non-controlled drug could appear to be quite a simple one. However, this is not the case: a new synthetic drug may be controlled in some Member States and not in others, and legal conditions on this issue are currently not set up in most Member States or at EU level.

Different, complementary approaches could be combined in order to tackle this issue.

Political level

In its conclusions of the risk assessment of 4-MTA, the enlarged Scientific Committee recommended that 'when a new synthetic drug is notified for risk assessment, arrangements be made for the provision of standard reference material and associated analytical data to forensic and toxicology laboratories within the European Union'.

This recommendation, supported by an explanatory memorandum from the Scientific Committee, needs to be discussed at political level (Commission, Council).

EWS level

Short-term practical solutions can be examined:

- firstly, the possibility for NFPs to inform the EMCDDA systematically of the name, location and contact person of the laboratory(ies) involved in the identification of a NSD following its

detection by seizure or another event. This information could then be forwarded by the EMCDDA to the laboratory network of the EWS at European level; and

- secondly, the organisation of permanent access to a library of GC/MS chromatograms and other analytical documents, on the basis of existing databases and other sources.

Further development is also required with regard to recording progress on the availability of reference samples.

8. The laboratory network

The importance of links with forensic and toxicology laboratories for the purpose of early detection and identification of a new synthetic drug has been underlined as a key aspect of an EWS. The two levels of work in this area should be distinguished.

National level

The setting up of a network of laboratories requires:

- mapping all the laboratories that could be involved, at any stage, in the process of detecting/identifying a NSD;
- taking into account various information flows – from a laboratory to the NFP and vice-versa, and between laboratories; and
- ensuring the maintenance of the information flow and the motivation and effectiveness of the network, by: the quality and relevance of the information dispatched to the laboratory network; easy and selective access to this information (electronic tools, links to databases, etc); and regular meetings (specialised, local, national).

EU level

The EMCDDA is in charge of providing the national EWS and their partner laboratories with:

- clear definitions of the scope of action, the role of each actor, agreed criteria and procedures for reporting, and feedback etc.;
- quality control (validation); and
- information and feedback in line with agreed definitions, criteria and procedures.

Future actions envisaged include:

- providing access to an online European inventory of NSD with links to existing national databases;
- documentary support, when available (scientific references, analytical papers, etc.);
- updating this guidance booklet taking into account new experience; and
- organising meetings.

9. Step-by-step procedure for data collection and transmission (JA article 3)

Level 1

As indicated in Part C, the detection of a new synthetic drug implies a rapid process of collection and transmission of the information.

Procedure for the transmission of information upon the first notification of a new synthetic drug

Two situations can be distinguished when a NSD is detected:

Situation 1: Member States where the NSD is encountered

In each Member State where the first detection of a NSD occurs, the information collected and rapidly sent to the EMCDDA should give the necessary elements to enable other Member States to check whether the drug is also present in their country (identification of the drug):

- a precise physical description (for visual identification of the product);
- the chemical composition;
- street name(s) when known;
- the event through which the new drug has been encountered (e.g. seizure, forensic analysis of fluids, pill test);
- the service (or programme, if pill testing) which has detected the drug;
- date and location of the event;
- quantities found; and

- other significant information if rapidly available (e.g. name of the laboratory which has identified a NSD).

Situation 2: Member States where the NSD is not detected at the time of its first notification in one (or more) other Member State(s)

In these countries, as soon as the first notification is received of a NSD in (an)other Member State(s), the national EWS should:

- quickly disseminate the information from the EMCDDA to the national EWS partners in order to enable them to identify the substance;
- actively check this early-warning information with the national EWS partners; and
- inform the EMCDDA about the results of the check-up as soon as it is completed.

If the NSD is found through this process, the country enters in Situation 1 as described above.

Procedure for new information to be collected after the first notification (both for Situations 1 and 2)

As soon as new information is collected which is liable to modify the profile of the information already known, this information should be transmitted without delay to the EMCDDA. Examples of such information are: fatality, non-fatal acute intoxication, significant seizure (in terms of volume, its particular location and/or circumstances), first findings from the forensic analysis of samples.

The types of information that can be compiled in a short report are:

- data which are not liable to modify the profile of the information already transmitted to and by the EMCDDA; and
- data which require a delay for reasons of quality check and validation.

The rhythm of reporting depends on the importance (nature, amount, frequency) of the information collected. The EMCDDA may always be consulted in case of doubt. The EMCDDA itself may also ask for an update (e.g. for the preparation of a Joint Progress Report with Europol).

Level 2

Part C lists the main items which require an information search in order to obtain a more complete picture of the characteristics, mode, context, possible scope and risks of use of a NSD.

This more in-depth data collection process should be followed up with a combination of rapid reporting and the transmission of compiled information. (In this situation the same procedure as the one followed after the first notification applies.)

For both levels 1 and 2, the information should, as far as possible, be validated by the NFPs as well as by the EMCDDA (see point 14 below).

10. Status of information

Two different types of information to be transmitted can be identified:

- information relevant to the scope of the Joint Action; and
- information not relevant to the scope of the Joint Action.

Consequently, two different statuses as regards the transmission of information by the EMCDDA can be distinguished:

- for action; and
- for information.

Synthetic drugs that do not fall within the scope of the Joint Action may be the subject of information [4] sent to the Reitox network because of risks or harm arising from, for example:

- their marketing form and promotion;
- their higher dosage than the one commonly expected by users;
- their mix with another drug (not a new synthetic drug) or with a dangerous additive (e.g. strychnine) which could pose a serious health risk; and
- the number of acute incidents in a short period of time suggesting a particular and unusual problem to be quickly identified.

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[4] If a NFP or the EMCDDA decides to provide the Reitox network with information on synthetic drugs not falling within the scope of the Joint Action, this cannot be done as a Joint Action procedure. It means that there is no obligation for any partner of the Joint Action's EWS to reply, to use or to report such information received from either the Centre or a NFP.

A NFP could also envisage providing such information to national partners as well as to the EMCDDA when the necessity arises for a broader dissemination for prevention purposes. The EMCDDA can then disseminate this information according to a number of criteria:

- quality check of the information, including its origin (official/non official);
- seriousness of an immediate or potential risk; and
- geographical dimension of a potential spread of the risk.

11. Cooperation between law-enforcement and health cultures

The collection and exchange of information between the EMCDDA and its Reitox network, on the one side, and Europol and its network of ENUs on the other, is based on the principles of specialisation and complementarity with full respect for each agency's mandate, work programme and core tasks. The EMCDDA's mandate for the collection and exchange of information, set out in its founding regulation, strictly excludes any data related to an identified or identifiable individual or to groups of individuals. The scope of the information requested from the EMCDDA and the NFPs and their national health and social partners for the purpose of the Joint Action is not related to or seeking intelligence data or other information exploitable as such. Cooperation between health and law-enforcement cultures is focused and limited to identifying new synthetic substances and the collection of data on their associated effects and potential risks. The fact that the EMCDDA and Europol are accountable to their respective mandatory bodies and to the relevant EU Institutions ensures that these obligations and rules are strictly respected.

12. Prevention

The Joint Action in fine aims to prevent the spread of the use and trafficking of potentially dangerous new substances within the context of its political orientation to decide whether or not control measures should be taken on new synthetic drugs in the shortest delay possible after they appear on the market.

The information on the health and social risks of synthetic drugs gathered through the early-warning mechanism, but which falls outside the scope of the Joint Action, may be of great value to health services and prevention networks as well as to current or potential users, with a view to preventing serious or fatal intoxications. Therefore, it is the EMCDDA's responsibility to

transmit to the NFPs all relevant information when it deems that the information at its disposal could serve this purpose. It is the responsibility of national authorities to decide whether or not to use such information for the purpose of preventive action at local or national level.

13. The use of electronic tools for the exchange of information

A key word emerging from the Joint Action is rapidity. Electronic tools offer a range of possibilities to transmit and exchange information 'in real time'. These tools can facilitate the distinction between the different levels of information, the status of the information and, moreover, can enhance the cooperation between all actors involved in the EWS.

Taking into account the fact that some NFPs have already implemented specialised EWS databases, an important development in the functioning of the EWS could be to organise a website. In doing so, the national partners in the EWS network could rapidly provide and have access to information respecting an agreed common definition of the status of each data type.

14. Validation of the information (cross-checking/quality assurance)

Information received by the NFP from national or local partners of the national EWS should be sent to the EMCDDA, and at the same time steps taken to validate it.

The EMCDDA checks the information received from a NFP before its transmission to the Reitox network.

In both cases, the quality check involves:

- identifying the primary source and/or secondary source of the information;
- quoting date and place when/where the information was issued, if available;
- assessing the reliability and quality of the information (ranking from scientific peer-reviewed publication, official or authorised sources to unconfirmed rumour); and
- assigning a status to the information (see point 10 above) before transmission.

Checklist on the functioning of a national early-warning system on new synthetic drugs

1. Capacity for the early detection of a NSD

Sensitiveness

Is the sensitiveness of the national EWS considered by the Reitox NFP to be sufficient to ensure that a new substance can be detected at an early stage in the country and that the relevant preliminary information can subsequently be collected and rapidly transmitted to the EMCDDA?

National coverage

How is this coverage organised? For example, is the coverage based upon the selection of a limited number of cities, districts, locally-based entities or 'spots', and/or field workers? Are they adequate, in terms of their location and respective capacity, to ensure that the web-like structure of the system can capture significant signals on the appearance of a new synthetic drug at an early stage and can report on this matter quickly?

Coordination body

Does the national EWS dispose of a well-identified coordination unit, with corresponding political support, which can act as the central point for information flows (collection, exchange and feedback), and which can also ensure and enhance an effective partnership between the Reitox channel and the law-enforcement side (national agencies and local police)? Check whether the law-enforcement information is directly channelled through the Europol National Unit or through other channels.

Information collection and transmission

Are data collection and analysis carried out on an ongoing basis (and not sporadically) and sent regularly to the EMCDDA, using the agreed instruments and mechanisms?

Development of the EWS network

Does the NFP regularly organise national meetings with the key partners of its EWS and does the NFP provide detailed information on the outputs to the EMCDDA?

Validation panels

How is the process organised for assessing the quality of the information collected from different sources, and how is this information validated in terms of its relevance for the purpose of the Joint Action's EWS?

Levels of mobilisation of the network

Does the EWS have selective criteria for the dissemination of information inside and outside the national network? Are there different levels of mobilisation of the network, e.g. alert messages, requests for collecting and/or disseminating specific information to local partners (informants, selected or all potential users in a setting, the whole EWS network, national health authorities)? What procedure is followed in the case of an alert message?

Sources of information

Which sources of information are used, for example, for:

- collecting data on availability and on prices of a NSD at user level?
- collecting information on patterns of use of a NSD and the relationship with other drug use patterns; on the characteristics of users and users groups and of the related settings; on the perceptions of users (expected effects, perceived effects) and of local services (observed effects, attitudes of users)?
- collecting information on the combination of the new synthetic drug with other licit or illicit drugs?

Level/rapidity of access

What is the level/rapidity of access to relevant services for obtaining information on the circumstances of an event (acute intoxication, local seizure, arrest, etc.) which has been reported to involve the use, possession, small or major trafficking of a new synthetic drug?

2. Main functions of an EWS

Is the effectiveness of the information flows (two-way, selective, rapid) ensured?

Is national coverage ensured?

Is the validation and rapid transmission of the relevant information to the EMCDDA ensured?

Is the maintenance of the network's response capacity provisioned for? Does it ensure that partners receive added value from their participation at national and EU levels (e.g. forums of exchange, electronic tools, access to database, targeted feedback, training and other supporting activities, etc.)?

Is there quick access to hard data on the frequency/quantities encountered from cases detected by law-enforcement services and forensic laboratories?

Is there access to information at user level through primary sources (outreach workers, pill-testing and/or other on-site prevention teams, low-threshold units, etc.)?

Is there access to clinical data through established links with secondary sources (poison units, hospital emergency wards, non-forensic laboratories, etc)?

Is there access to additional information on circumstances of the cases detected (local police, judicial system, etc.)?

Text of the Joint Action

97/396/JHA: Joint Action of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and the control of new synthetic drugs
Official Journal L 167, 25/06/1997, pp. 1–3

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, in particular Article K.3 (2) (b) thereof,

Having regard to the initiative of the Netherlands,

NOTING that the Dublin European Council welcomed the progress report on drugs on 13 and 14 December 1996 and endorsed the action proposed in that report, including the proposal to tackle the problem of synthetic drugs at three levels, namely, through legislation, practical cooperation against production and trafficking and international cooperation,

REFERRING to the Joint Action 96/750/JHA of 17 December 1996, adopted by the Council on the basis of Article K.3 of the Treaty on the European Union, concerning the approximation of the laws and practices of the Member States of the European Union to combat drug addiction and to prevent and combat illegal drug trafficking [1],

REFERRING in particular to Article 5 of the said Joint Action, which provides that the Member States shall endeavour to draft convergent legislation to the extent necessary to make up legal ground or fill legal vacuums as regards synthetic drugs. In particular they shall promote the establishment of a rapid information system to enable such drugs to be identified as substances liable to be prohibited as soon as they appear anywhere in a Member State,

CONSIDERING that the particular dangers inherent in the development of synthetic drugs require rapid action by the Member States,

CONSIDERING that when new synthetic drugs are not brought within the scope of criminal law in all Member States, problems may arise in the international cooperation between the judicial authorities and law enforcement

[1] OJ No L 342, 31.12.1996, p. 6.

agencies of the Member States owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State,

CONSIDERING that from an inventory drawn up since the adoption of the said Joint Action it can be concluded that new synthetic drugs have appeared within the Member States,

CONSIDERING that common action can be taken only on the basis of reliable information on the emergence of new synthetic drugs and the results of expert assessment of the risks caused by the use of the new synthetic drugs and implications of submitting such drugs under control,

CONSIDERING that it is therefore necessary to set up a common mechanism permitting expeditious action, in taking necessary measures or introducing controls on new synthetic drugs, on the basis of a rapid exchange of information on new synthetic drugs emerging in the Member States and the common assessment of the risks thereof,

WITHOUT PREJUDICE to the powers of the European Community,

HAS ADOPTED THIS JOINT ACTION:

Article 1: Purpose

This Joint Action aims at the creation of a mechanism for rapid exchange of information on new synthetic drugs and the assessment of their risks in order to permit the application of the measures of control on psychotropic substances, applicable in the Member States, equally to new synthetic drugs. This mechanism will be jointly implemented in accordance with the procedures established hereunder.

Article 2: Scope

This Joint Action concerns new synthetic drugs which are not currently listed in any of the Schedules to the 1971 United Nations Convention on Psychotropic Substances, and which pose a comparable serious threat to public health as the substances listed in Schedules I or II thereto and which have a limited therapeutic value. It relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [2] and Council Directive 92/109/EEC of 14

[2] OJ No L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EEC) No 3769/92 (OJ No L 383, 29.12.1992, p.17).

December 1992 on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances [3] provide for a Community regime.

Article 3: Exchange of information

1. Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the production, traffic and use of new synthetic drugs to the Europol Drugs Unit (EDU) of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), taking into account the respective mandates of these two bodies. The EDU and and the EMCDDA shall collect the information received and the communicate this information in an appropriate manner immediately to each other and to the Europol National Units and the representatives of the Reitox-network of the Member States, to the Commission and the European Agency for the Evaluation of Medicinal Products.

2. The information referred to in paragraph 1 shall include:

(a) – a chemical and physical description, including the name under which a new synthetic drug is known,

– information on the frequency, circumstances and/or quantities in which a new synthetic drug is encountered,

– a first indication of the possible risks associated with the new synthetic drug, and, as far as possible:

(b) – information on the chemical precursors,

– information on the mode and scope of the established or expected use of the new synthetic drug as a psychotropic substance,

– information on other use of the new synthetic drug and the extent of such use,

– further information on the risks of use of the new synthetic drug, including the health and the social risks.

Article 4: Risk assessment

1. At the request of one of the Member States or the Commission, the EMCDDA shall convene a special meeting under the auspices of the Scientific Committee extended with experts nominated by the Member States and

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[3] OJ No L 370, 19.12.1992, p. 76. Directive as amended by Directive 93/46/EEC (OJ No L 159, 1.7.1993, p. 134).

to which representatives of the Commission, the EDU and the European Agency for the Evaluation of Medicinal Products shall be invited.

This committee shall assess the possible risks, including the health and social risks, caused by the use of, and traffic in, new synthetic drugs, and possible consequences of prohibition.

2. The risk assessment shall be carried out on the basis of information provided by the Member States, the Commission, the EMCDDA, the EDU of the European Agency for the Evaluation of Medicinal Products and taking into account all factors which, according to the 1971 United Nations

Convention on Psychotropic Substances, would warrant the placing of a substance under international control.

3. On completion of the risk assessment, a report will be drawn up on the findings. In the report all aspects shall be addressed. All opinions on these aspects shall be reflected in the report.

Article 5: Procedure for bringing specific new synthetic drugs under control

1. The Council may, on the basis of an initiative to be presented within a month from the date on which the report of the results of the risk assessment pursuant to Article 4 (1) is established and acting in accordance with Article K.3 (2) (b) of the Treaty, adopt unanimously a decision defining the new synthetic drug or drugs which are to be made subject to necessary measures of control.

If the Commission deems it not necessary to present an initiative to have the new synthetic drug or drugs submitted to control measures, it shall present a report to the Council explaining its views.

The Member States undertake, in accordance with the decision taken by the Council, within such delay as that decision may specify, to take the necessary measures in accordance with their national law to submit these new synthetic drugs to control measures and criminal penalties as provided under their legislation complying with their obligations under the 1971 United Nations Convention on Psychotropic Substances with respect to substances listed in Schedules I or II thereto.

2. Nothing in this Joint Action shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new synthetic drug has been identified by a Member State.

3. The Presidency shall each year submit a report to the Council on the implementation of the decisions adopted by the Council on the basis of paragraph 1.

Article 6: Publication and entry into force

This Joint Action shall be published in the Official Journal.

It shall enter into force on the day of its publication.

Done at Luxembourg, 16 June 1997.

For the Council
The President
H. VAN MIERLO